

## CLAIMS:

1. An access instrument for accessing an anatomic space between anatomic surfaces in a patient's body comprising:

an elongated access instrument body formed of an elastomer extending between a access instrument body proximal end and a access instrument body distal end, the elongated access instrument body having a access instrument body axis, a access instrument body width in a width direction with respect to the access instrument body axis, and a access instrument body thickness in a thickness direction substantially orthogonal to the width direction, the access instrument body width exceeding the access instrument body thickness enabling bending of the access instrument body in the thickness direction and resisting bending of the access instrument body in the width direction, the elongated access instrument body enclosing an inflation lumen extending from the access instrument body proximal end through the access instrument body to an inflation lumen distal end opening and a working lumen extending from the access instrument body proximal end through the access instrument body to the access instrument body distal end; and

a distal header coupled to the access instrument body distal end comprising a header body supporting a header plate extending laterally of the access instrument body axis in the width direction to a atraumatic plate rim, the header plate having a first plate side bounded by the atraumatic plate rim, the header body enclosing a header lumen extending between the working lumen at the access instrument body distal end and a working lumen exit port through the first plate side, and an inflatable balloon mounted to the plate and adapted to be inflated by introduction of inflation media through the inflation lumen distal end opening into an inflation space between the balloon and at least a portion of the first plate side,

whereby the inflation of the inflatable balloon expands an anatomic space between anatomic surfaces and disposes the working lumen exit port spaced from an anatomic surface.

2. The access instrument of Claim 1, wherein the balloon supported by the header plate substantially surrounds the working lumen exit port.

3. The access instrument of Claim 1, wherein the header body and header plate extend distally from the access instrument body, whereby a distal segment of the atraumatic plate rim separates anatomic surfaces along a pathway to the anatomic space as the access instrument body is advanced into the incision and along the pathway.

4. The access instrument of Claim 1, wherein:  
the balloon supported by the header plate substantially surrounds the working lumen exit port and comprises a proximal balloon segment enclosing a proximal balloon segment inflation space and a distal balloon segment enclosing a distal balloon segment inflation space; and

the inflation lumen of the access instrument body comprises a proximal balloon segment inflation lumen having an inflation lumen distal end opening into the proximal balloon segment inflation space and a distal balloon segment inflation lumen having an inflation lumen distal end opening into the distal balloon segment, whereby the proximal and distal balloon segments can be selectively inflated by inflation media introduced into the proximal or distal balloon segment inflation space.

5. The access instrument of Claim 1, wherein the access instrument body incorporates a light pipe having a light pipe proximal end adapted to be coupled to a light source external to the patient's body and extending to a light pipe distal end, and the distal header comprises a light emitter coupled to the light pipe distal end that emits light generated by the light source and conducted through the light pipe in a region adjoining the working lumen exit port.

6. The access instrument of Claim 5, wherein the balloon is substantially transparent to emitted light.

7. The access instrument of Claim 5, wherein the light emitter comprises a light ring disposed in the first plate side in proximity to the balloon and the working lumen exit port.

8. The access instrument of Claim 7, wherein the light ring is formed having a faceted outer surface for selectively directing light in the region.

9. The access instrument of Claim 5, wherein the light emitter is formed having a faceted outer surface for selectively directing light in the region.

10. The access instrument of Claim 1, wherein the first plate side is substantially planar and surrounded by the atraumatic plate rim, and the first plate side is substantially in parallel to the access instrument body axis, whereby the first plate side is disposable in proximity to a first anatomic surface when the inflatable balloon is deflated, and is disposed away from the first anatomic surface when the inflatable balloon is inflated.

11. An epicardial lead access instrument for implanting an epicardial lead into the myocardium at an epicardial implantation site between the epicardium and the pericardium accessed through the thorax from a skin incision, the epicardial lead of the type having an elongated lead body extending between at least one proximal electrical connector element and a distal fixation mechanism extending from a distal electrode head, the lead body supporting at least one electrode coupled through an electrical conductor to a proximal electrical connector element, the access instrument comprising:

an elongated access instrument body formed of an elastomer extending between a access instrument body proximal end and a access instrument body distal end, the access instrument body having a access instrument body axis, a access instrument body width in a width direction with respect to the access instrument body axis, and a access instrument body thickness in a thickness direction substantially orthogonal to the width direction, the access instrument

body width exceeding the access instrument body thickness enabling bending of the access instrument body in the thickness direction and resisting bending of the access instrument body in the width direction, the access instrument body enclosing an inflation lumen extending from the access instrument body proximal end through the access instrument body to an inflation lumen distal end opening and a working lumen extending from the access instrument body proximal end through the access instrument body to the access instrument body distal end dimensioned to enable passage of the lead body and distal fixation mechanism therethrough; and

a distal header coupled to the access instrument body distal end comprising a header body supporting a header plate extending laterally of the access instrument body axis in the width direction to a atraumatic plate rim, the header plate having a first plate side bounded by the atraumatic plate rim, the header body enclosing a header lumen extending between the working lumen at the access instrument body distal end and a working lumen exit port through the first plate side, and an inflatable balloon mounted to the header plate adapted to be inflated by introduction of inflation media through the inflation lumen distal end opening into an inflation space between the balloon and at least a portion of the first plate side,

whereby the access instrument is adapted to be advanced through the thorax from the skin incision between the epicardium and the pericardium to dispose the deflated balloon and first plate side toward the epicardium at the epicardial implantation site to enable inflation of the balloon to position the working lumen port facing toward and spaced from the epicardium allowing passage of the distal fixation mechanism from the working lumen exit port and fixation to the epicardium.

12. The access instrument of Claim 11, wherein the balloon supported by the header plate substantially surrounds the working lumen exit port.

13. The access instrument of Claim 11, wherein the header body and header plate extend distally from the access instrument body, whereby a distal segment of the atraumatic plate rim separates the pericardium from the epicardium as the access instrument body is advanced into the incision and into the pericardial space to a selected epicardial surface site.

14. The access instrument of Claim 11, wherein:  
the balloon supported by the header plate comprises a proximal balloon segment enclosing a proximal balloon segment inflation space and a distal balloon segment enclosing a distal balloon segment inflation space; and  
the inflation lumen of the access instrument body comprises a proximal balloon segment inflation lumen having an inflation lumen distal end opening into the proximal balloon segment inflation space and a distal balloon segment inflation lumen having an inflation lumen distal end opening into the distal balloon segment, whereby the proximal and distal balloon segments can be selectively inflated by inflation media introduced into the proximal or distal balloon segment inflation space facilitating advancement of the distal fixation mechanism into engagement with the epicardium and retraction of the access instrument over the lead body without dislodging the distal fixation mechanism.

15. The access instrument of Claim 14, wherein the distal fixation mechanism comprises a fixation helix adapted to be screwed through the epicardium into the myocardium.

16. The access instrument of Claim 14, wherein the cardiac lead comprises a suture-on, steroid button, pacing lead.

17. The access instrument of Claim 11, wherein the access instrument body incorporates a light pipe having a light pipe proximal end adapted to be coupled to a light source external to the patient's body and extending to a light pipe distal end, and the distal header comprises a light emitter coupled to the light pipe distal end that emits light generated by the light source and conducted through the light pipe in a region adjoining the working lumen exit port to illuminate the pericardial space and the epicardial surface .

18. The access instrument of Claim 17, wherein the balloon is substantially transparent to emitted light.

19. The access instrument of Claim 18, wherein the light emitter comprises a light ring disposed in the first plate side in proximity to the balloon and the working lumen exit port.

20. The access instrument of Claim 19, wherein the light ring is formed having a faceted outer surface for selectively directing light in the region.

21. The access instrument of Claim 17, wherein the light emitter comprises a light ring disposed in the first plate side in proximity to the balloon and the working lumen exit port.

22. The access instrument of Claim 21, wherein the light ring is formed having a faceted outer surface for selectively directing light in the region.

23. The access instrument of Claim 17, wherein the light emitter is formed having a faceted outer surface for selectively directing light in the region.

24. The access instrument of Claim 11, wherein the first plate side is substantially planar and surrounded by the atraumatic plate rim, and the first plate side is substantially in parallel to the access instrument body axis, whereby the first plate side is disposable in proximity to the epicardium when the inflatable balloon is deflated, and is disposed away from the epicardium when the inflatable balloon is inflated.

25. The access instrument of Claim 24, wherein the inflation of the inflatable balloon facilitates expansion of the pericardial space, visualization of the epicardium and cardiac vessels to locate a epicardial surface site, and positioning, introduction, and fixation of the distal fixation mechanism of the cardiac lead.

26. The access instrument of Claim 25, wherein the distal fixation mechanism comprises a fixation helix adapted to be screwed through the epicardium into the myocardium.

27. The access instrument of Claim 25, wherein the cardiac lead comprises a suture-on, steroid button, pacing lead.

28. The access instrument of Claim 11, wherein the inflation of the inflatable balloon facilitates expansion of the pericardial space, visualization of the epicardium and cardiac vessels to locate a epicardial surface site, and positioning, introduction, and fixation of the distal fixation mechanism of the cardiac lead.

29. The access instrument of Claim 11, wherein the distal fixation mechanism comprises a fixation helix adapted to be screwed through the epicardium into the myocardium.

30. The access instrument of Claim 11, wherein the cardiac lead comprises a suture-on, steroid button, pacing lead.

31. A method of enlarging an anatomic space within the human body between first and second anatomic surfaces and accessing a selected site of the first anatomic surface comprising:

providing an access instrument comprising:

an elongated access instrument body formed of an elastomer extending between a access instrument body proximal end and a access instrument body distal end, the access instrument body having a access instrument body axis, a access instrument body width in a width direction with respect to the access instrument body axis, and a access instrument body thickness in a thickness direction substantially orthogonal to the width direction, the access instrument body width exceeding the access instrument body thickness enabling bending of the access instrument body in the thickness direction and resisting bending of the access instrument body in the width direction, the access instrument body enclosing an inflation lumen extending from the access instrument body proximal end through the access instrument body to an inflation lumen distal end opening and a working lumen extending from the access instrument body proximal end through the access instrument body to the access instrument body distal end; and

a distal header coupled to the access instrument body distal end comprising a header body supporting a header plate extending laterally of the access instrument body axis in the width direction to a atraumatic plate rim, the header plate having a first plate side bounded by the atraumatic plate rim, the header body enclosing a header lumen extending between the working lumen at the access instrument body distal end and a working lumen exit port through the first plate side, and an inflatable balloon mounted to the plate and adapted to be inflated by introduction of inflation media through the inflation lumen distal end opening into an inflation space between the balloon and at least a portion of the first plate side,



surgically creating an incision into the anatomic space between the first and second anatomic surfaces;

inserting the distal header through the incision with the first plate side disposed facing the first anatomic surface;

advancing the distal header through the anatomic space between the first and second anatomic surfaces with the first plate side disposed facing the first anatomic surface;

inflating the balloon to expand the anatomic space between the first and second anatomic surfaces;

introducing one of a visualization instrument through the working lumen to visualize the anatomic space and the first anatomic surface to select a site of the first anatomic surface, a medical instrument through the working lumen for performing a medical procedure, an implantable medical device through the working lumen into the anatomic space, and a therapeutic drug or diagnostic agent through the working lumen into the anatomic space.

32. The method of Claim 31, wherein the balloon supported by the header plate substantially surrounds the working lumen exit port, and the inflating step comprises inflating the balloon around the working lumen exit port.

33. The method of Claim 31, wherein the header body and header plate extend distally from the access instrument body, and the advancing step comprises advancing the distal segment of the atraumatic plate rim while the balloon is deflated to separate the first and second anatomic surfaces.

34. The method of Claim 31, further comprising emitting light from the distal header to illuminate at least a region of the anatomic space and first anatomic surface.

35. The method of Claim 34, wherein the balloon is substantially transparent to emitted light.

36. The method of Claim 34, wherein:

the access instrument body incorporates a light pipe having a light pipe proximal end and extending to a light emitter at the distal header coupled to the light pipe; and

the emitting step comprises coupling a light source outside the patient's body to the light pipe proximal end to transmit light through the light pipe and emitter into a region of the anatomic space adjoining the working lumen exit port.

37. The method of Claim 36, wherein the light emitter comprises a light ring disposed in the first plate side in proximity to the balloon and the working lumen exit port.

38. The method of Claim 37, wherein the light ring is formed having a faceted outer surface for selectively directing light in the region.

39. The method of Claim 34, wherein the light emitter is formed having a faceted outer surface for selectively directing light in the region.

40. The method of Claim 34, wherein the introducing step comprises: advancing a visualization instrument through the working lumen to the working lumen distal exit port; and

operating the visualization instrument during the emission of light to obtain a visual image of the illuminated region of the anatomic space or first anatomic surface.

41. The method of Claim 31, wherein the first plate side is substantially planar and surrounded by the atraumatic plate rim, and the first plate side is substantially in parallel to the access instrument body axis, whereby the first plate side is disposable in proximity to the first anatomic surface when the inflatable balloon is deflated, and is disposed away from the first anatomic surface when the inflatable balloon is inflated.

42. The method of Claim 31, wherein:

the balloon supported by the header plate substantially surrounds the working lumen exit port and comprises a proximal balloon segment enclosing a proximal balloon segment inflation space and a distal balloon segment enclosing a distal balloon segment inflation space;

the inflation lumen of the access instrument body comprises a proximal balloon segment inflation lumen having an inflation lumen distal end opening into the proximal balloon segment inflation space and a distal balloon segment inflation lumen having an inflation lumen distal end opening into the distal balloon segment; and

the inflating step comprises selectively introducing inflation media through at least one of the proximal and distal inflation lumens to inflate at least one of the proximal and distal balloon segments.

43. The method of Claim 42, wherein:

the inflating step comprises inflating the proximal balloon segment while the distal balloon segment is deflated to provide a distal opening into the anatomic space; and

the introducing step comprises advancing one of a medical instrument or medical device distally from the working lumen exit port through the distal opening distally of the instrument header.

44. The method of Claim 43, further comprising retracting the access instrument over the one of the medical instrument or medical device extending from the working lumen exit port and proximally through the working lumen. .

45. The method of Claim 42, wherein the inflating step comprises inflating the proximal balloon segment while the distal balloon segment is deflated to provide a distal opening into the anatomic space; and further comprising:

retracting the access instrument over a medical instrument or medical device extending from the working lumen exit port and proximally through the working lumen.

46. The method of Claim 42, wherein the introducing step comprises:  
advancing an electrical medical lead of the type having an elongated lead body extending between at least one proximal electrical connector element and a distal fixation mechanism extending from a distal electrode head, the lead body supporting at least one electrode coupled through an electrical conductor to a proximal electrical connector element, through the working lumen;

advancing the distal fixation mechanism from the working lumen exit port into the anatomic space while the proximal and distal balloon segments are inflated;

affixing the distal fixation mechanism to the first anatomic surface;

deflating the distal balloon segment; and

retracting the access instrument over the electrical medical lead body extending from the working lumen exit port and proximally through the working lumen.

47. The method of Claim 46, wherein the anatomic space is the epicardial space between the epicardium and the pericardium surrounding the heart, and the first anatomic surface is the epicardium.

48. The method of Claim 47, wherein the distal fixation mechanism comprises a fixation helix, and the affixing step comprises rotating the fixation helix to screw the fixation helix through the epicardium into the myocardium.

49. The method of Claim 31, wherein the introducing step comprises:  
advancing an electrical medical lead of the type having an elongated lead body extending between at least one proximal electrical connector element and a distal fixation mechanism extending from a distal electrode head, the lead body

supporting at least one electrode coupled through an electrical conductor to a proximal electrical connector element, through the working lumen;

advancing the distal fixation mechanism from the working lumen exit port into the anatomic space while the balloon is inflated;

affixing the distal fixation mechanism to the first anatomic surface;

deflating the balloon; and

retracting the access instrument over the electrical medical lead body extending from the working lumen exit port and proximally through the working lumen.

50. The method of Claim 49, wherein the distal fixation mechanism comprises a fixation helix, and the affixing step comprises rotating the fixation helix to screw the fixation helix through the epicardium into the myocardium.